



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Washington, DC 20204

MAR 30 2000

3 2 8 6 '00 APR 25 P 2:39

Ms. Deborah Shur Trinker  
Vice President of Regulatory Affairs  
and Assistant General Counsel  
Rexall Sundown, Inc.  
6111 Broken Sound Parkway, NW  
Boca Raton, Florida 33487-3693

Dear Ms. Trinker:

This is in response to your letter of March 21, 2000 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Rexall Sundown, Inc. is making the following claims, among others, for the following products:

**Odorless Garlic (Sundown)**

"...helps maintain normal cholesterol levels..."

**Garlic XTRA (Sundown)**

"...promotes healthy heart function and cholesterol levels"

"...promote healthy cholesterol levels..."

"...maintain health cholesterol levels"

**Odor-Free Garlic (Sundown)**

"...promotes healthy heart function and cholesterol levels"

"...maintain normal cholesterol levels..."

**Garlic (Rexall)**

"...promotes healthy heart function and cholesterol levels"

"...maintain normal cholesterol levels..."

**Garlic Oil, Garlic Oil 1500 (Rexall)**

"...maintain healthy serum cholesterol levels"

**Advanced Formula Garlic Odor-Controlled with hawthorn, Korean Ginseng,  
Vitamin C and Chromium Picolinate (Thompson)**

"...promotes healthy heart and cholesterol levels."

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21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products suggest that they are intended to treat, prevent, cure or mitigate disease, namely hypercholesterolemia. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,

John B. Foret  
Director  
Division of Compliance and Enforcement  
Office of Nutritional Products, Labeling,  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300  
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200  
FDA, Florida District Office, Office of Compliance, HFR-SE240

cc:

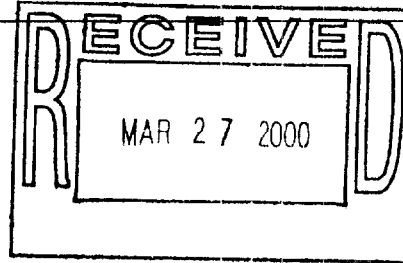
HFA-224 (w/incoming)  
HFA-305 (docket 97S-0163)  
HFS-22 (CCO)  
HFS-800 (r/f, file)  
HFS-811 (r/f, file)  
HFD-310 (BWilliams)  
HFD-314 (Aronson)  
HFS-605  
HFV-228 (Benz)  
GCF-1 (Dorsey, Barnett, Nickerson)  
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6111 Broken Sound Parkway NW  
Boca Raton, FL 33487-3693  
(561) 241-9400  
Fax (561) 995-5188

March 21, 2000

Food and Drug Administration  
Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
200 C Street, SW  
Washington, DC 20204



Dear Sirs:

Notice is hereby given that Rexall Sundown, Inc. ("Sundown") located at 6111 Broken Sound Parkway, N.W., Boca Raton, Florida 33487 has marketed a dietary supplement under the Rexall, Thompson and Sundown brand names bearing the following statement(s) on the label and/or in the labeling:

Garlic Oil (Sundown): [It] promotes healthy cardiovascular and circulatory function.

Garlic 1500 (Sundown): [It] promotes healthy cardiovascular function and general well-being.

Odorless Garlic (Sundown): [It] promotes healthy cardiovascular function and general well-being. It helps maintain normal cholesterol levels and aids in healthy circulation and digestion.

Garlic XTRA (Sundown): [It] promotes healthy heart function and cholesterol levels. It has been shown to help promote healthy cholesterol levels, cardiovascular health and circulatory function. The ingredients in Sundown Garlic XTRA help maintain healthy cholesterol levels. Sundown Garlic XTRA features standardized Garlic concentrate (standardized to yield 1% allicin, 2.4mg per tablet) blended with Hawthorn, Korean Ginseng, Vitamin C and Chromium Picolinate, which work in harmony to help promote healthy heart function and cholesterol levels.

Odor-Free Garlic (Sundown): [It] naturally promotes healthy heart function and cholesterol levels. Garlic is a member of the lily family and has been used as a health aid since the dawn of civilization. Garlic helps maintain normal cholesterol levels and healthy cardiovascular and circulatory function. Garlic's extensive health-enhancing properties also include immune system benefits.

Garlic (Rexall): [It] naturally promotes healthy heart function and cholesterol levels. Garlic is a member of the lily family and has been used as a health aid since the dawn of civilization. Garlic helps maintain normal cholesterol levels and healthy cardiovascular and circulatory function. Garlic's extensive health-enhancing properties also include immune system benefits.

Garlic Oil, Garlic Oil 1500 (Rexall): Garlic helps maintain healthy serum cholesterol levels. Garlic promotes healthy circulatory, cardiovascular and digestive health.

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Advanced Formula Garlic Odor-Controlled with Hawthorn, Korean Ginseng, Vitamin C and Chromium Picolinate (Thompson): [It] promotes healthy heart and cholesterol levels.

The undersigned certifies that the information contained in this notice is complete and accurate and that Sundown has substantiation that the statement is truthful and not misleading. Pursuant to § 101.93 (a)(1), two copies of this notification are enclosed.

Sincerely,

A handwritten signature in black ink, appearing to read "Deborah Shur Trinker".

Deborah Shur Trinker  
Vice President of Regulatory Affairs  
and Assistant General Counsel

Enclosure